K032741

AXON
SYSTEMS

DEC 16 2003

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11. 510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

Name:	Howard Bailin Vice President, C.O.O.
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Phone:	631 436 5112
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Email:	hbailin@axonsystems.com
Proprietary Name:	EpochXP Neurological Workstation EpochXP Lite Neurological Workstation
Common Name:	Electroencephalograph (EEG Monitor), Evoked Potential (SEP, BAEP, AEP, VEP, MEP) System, EMG Monitor
Classification Name:	Electroencephalograph, Evoked Response, Electromyograph
Classification:	Class II (Performance Standards) Panels: Neurology, Anesthesiology Number: 882.1400 Electroencephalograph 882.1420 Electroencephalograph (EEG) Signal Spectrum Analyzer Electromyograph Monitor Stimulator, Electrical, Evoked Response Stimulator, Photic, Evoked Response Stimulator, Sonic, Evoked Response Procodes: GWQ, GWE, GWF, OLT, GWJ,
Predicate Devices	EpochXP (K022785) Digitimer D185 (K020400)

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K032791

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Description:

The EpochXP Neurological Workstation provides continuous monitoring of brain and neural pathways intraoperatively or in the intensive care unit. The system has been designed to meet the demanding requirements for comprehensive neurological monitoring in the electrically hostile operating room and critical care environments.

The EpochXP can be used to monitor neurological data using either individual or multimodality EEG, EMG and evoked potential test protocols. The main EpochXP system components include: CPU, interface enclosure, data acquisition module, sensory and motor electrical stimulator, stimulator extension boxes, LED goggles and insert earphones.

Recording electrodes, placed on the patient, are connected the digital preamplifier (data acquisition module) The signal is amplified, filtered, optically isolated and converted to a digital signal. The digitized data is then routed to the digital signal processing (DSP) board located in the interface enclosure. The DSP processes the data and controls timing for the stimulators. The CPU acts as the user interface for setting parameters and controls and for display of the processed data.

Data from external devices, such as vital signs monitors, can be imported to the EpochXP display screen, allowing the operator to correlate changes in neurologic function with the patient's systemic vital signs. In addition, a display window may be opened to observe the surgeon's microscope view on screen. The EpochXP is network compatible for data review within the hospital and permits secure information access over the Internet.

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Appendix I
510(k) Summary

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Indications for Use:

The EpochXP is intended for use in the operating room and critical care areas for neurological monitoring and assessment. The instrument uses EEG, evoked potentials and EMG techniques to provide health care professionals with information to help assess a patient's neurological status during surgery or long term monitoring in the ICU.

Based on the clinical data and technical information provided in this 510(k) and the safety and effectiveness criteria of the design and development process, validated and verified, we claim the EpochXP (EpochXP Lite) Neurological Workstation to be safe, effective and substantially equivalent to the predicate device noted.

The EpochXP with added motor evoked potential stimulation is similar in concept and function to the legally marked devices, EpochXP (K022785) and Digitimer D185 (K020400), class II devices.

The addition of transcranial motor evoked potential stimulation modality incorporated in this product is designed to meet the current and expanding demands of health care professionals for more effective neurological monitoring without compromising safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Howard Bailin
Vice President
Axon Systems, Inc.
400-2200 Oser Avenue
Hauppuage, New York 11788

APR - 9 2012

Re: K032741
Trade/Device Name: EpochXP Neurological Monitor
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF, GWE, GWJ, GWQ, OLT
Dated (Date on orig SE ltr): November 17, 2003
Received (Date on orig SE ltr): November 18, 2003

Dear Mr. Bailin:

This letter corrects our substantially equivalent letter of December 16, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K032741

Device Name EpochXP Neurological Monitor

Indications for Use

The EpochXP Neurological Monitor is intended for use in the operating room and critical care areas for neurological monitoring and assessment. The instrument uses EEG, evoked potentials and EMG techniques to provide health care professionals with information to help assess a patient's neurological status and guide treatment during surgery or long term monitoring in the ICU

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032741

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)